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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,952

Applicant(s)

HARRIS ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 25, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8-1-06; 10-21-04</u> . | 6) <input type="checkbox"/> Other: _____ |

The abstract of the disclosure is objected to because on line 5, "said blood vessel" involves legal phraseology. Correction is required (MPEP § 608.01(b)).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second end formation and second end chamber as set forth in claim 7, 8, and others must be shown or the features canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s) (*In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 23 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,221,101 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present features are set forth in or would have been immediately obvious from the limitations of the patent claims. The enlarged chamber having a greater diameter, at least in one dimension, would have been obvious, if not inherent, in order to render the chamber enlarged relative to the tube as claimed in the patent.

Claim 23 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,861,026. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons similar to those given above. Patent claim 7 does not specify that the PTFE be expanded, but such a material (ePTFE) was quite common in the art at the time of the present invention and would have been obvious from its beneficial properties known to the ordinary practitioner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 4-6, and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, line 2, “the axis” and “the tube” lack proper antecedent bases; on line 4, “said first diameter comprising a heel and a toe” is confusing as to the scope, because a “diameter” is merely a line segment or a length of a line segment, so it is not seen how such a geometrical term can have “a heel and a toe”; similar problems exist in claim 8. Likewise, in claims 5 and 10, it is not understood how a diameter can have opposing sides that are generally outwardly convex. Claim 6 is vague and indefinite as to which of the first diameters (claim 1, line 3; claim 2, line 2) and second diameters (claim 1, line 4; claim 2, lines 2-3) are being referenced.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rayhanabad, US 4,712,551, which discloses a generally tubular portion **12** and an end formation **32**. The tubular portion **12** tapers from the distal end **16** to the inlet tip **20** (column 5, lines 33-36). Because the mouth **22** defines an opening of elliptical cross section (column 5,

lines 25-32) and because of the physical structure of the aorta, the end formation **32** defines a non-circular open-end perimeter. Regarding claim 2 and others, various axes are evident from the geometry of the “tube”, and the components inserted into the aorta **18** possess several concave and convex surfaces. Regarding claim 3, the difference in internal diameters between the mouth **22** and the aorta **18** inherently creates non-laminar movement of blood. Regarding claim 6: column 5, lines 29-32 and 38-40. Regarding claim 7 and others: attention is directed to the embodiment of Figure 8, for example. Regarding claim 18 and others, the first diameter portion is view as comprising the intermediate section **17**; as for claim 21, the first diameter portion additionally comprises the branch **51** and the distal and intermediate portions of the tubular portion **12'**.

Claims 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rayhanabad, US 4,712,551. PTFE materials were well known in the art at the time of the present invention and would have been obvious from their advantageous physical properties and hemocompatibility, with Rayhanabad being open to various suitable materials (column 9, lines 5-9).

Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Papazoglou, WO 95/34255 A1: page 10, lines 9-32; drawings. The configuration depicted in Figure 10, for example, includes an enlargement at stent **66** with a diameter larger than a diameter at “the remaining unexpanded portion of proximal portion **32**” (page 16, lines 7-8) and larger than a diameter of distal portions **33** and **34**. Claim 23 is also clearly met by the embodiment illustrated in Figure 3.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and sometimes on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse
Primary Examiner
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